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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/816,711 | 04/02/2004 | William J. Flickinger | P-11168.00 | 1190 |
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| MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924 | | | EXAMINER GEDEON, BRIAN T | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3766 | |

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/816,711

Applicant(s)

FLICKINGER ET AL.

Examiner

Brian T. Gedeon

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-7,10,16,20-23,25 and 27 is/are rejected.
- 7) ☒ Claim(s) 1-15 and 17-31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 August 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/30/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 20-31 are objected to because of the following informalities: two claims numbered 20 appear in application, as well as two claims numbered 27, all subsequent claims are assumed as misnumbered. Appropriate correction is required.
2. Claims 23, 24, and 28-31 are objected to because of the following informalities: claim 23, as written, depends on claim 1. Claim 1 is already modified by such a limitation from claim 7. Please check for appropriate dependency of claim. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 4, 10, 20, 21, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hooper et al. (US Patent no. 5,257,622).

In regard to claims 1 and 20, Hooper et al. discloses a coupling process and device for an implantable pulse generator 10 and its associated lead 12. The process involves insertion of the proximal end of the lead 12 into the connector block 14 of the implantable pulse generator 10. The connector block 14 is shown in figure 1, with the proximal end of the lead 12 inserted. The surface of the lead 12 connector is effectively

mating with the inner surface of the connector block 14. Figure 1 also shows that the inner surface diameter of the connector block 14 is larger than the diameter of the lead 12. A collar 29 is used to fixedly position the lead 12 within the connecting block 14, col 3 lines 40-48, and can be slidably inserted into the open cavity of the insertion block. However, the collar 29 is not slidably engageable with the lead 12, but preformed onto the lead 12, col 3 line 18. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to devise such a connector assembly for securing an implantable medical lead with an implantable stimulation device since Hopper et al have described the essential structure of the device. Further, it would have been obvious to one of ordinary skill in the art to use a collar to allow for small insertion forces and large removal forces, regardless if the collar was integrally fixed to the lead or "slidable engageable" since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin V. Erlichman*, 168 USPQ 177, 179.

In regard to claims 4 and 21, in figure 2, the collar 29 is shown as being tapered.

In regard to claims 10 and 25, the collar 29 is shown as being tapered, and used with a retention ring 11, col 2 lines 58-59.

4. Claims 5 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hooper et al. (US Patent no. 5,257,622) in view of Appling et al. (US Patent no. 5,651,776).

In regards to claims 5 and 22, Hooper et al. substantially describes the invention as claimed except for the threads on the header for engaging the collar. Appling et al.

discloses a luer-type connector, which is similar to the structure on the instant invention. The connector described by Appling et al. has a hub 12, stem 14, and a collar 16. The hub 12 has thread 36 and 38, which engage, with the threads 32 and 24 of the collar 16. Therefore it would have been obvious to one of ordinary skill in the art at the time invention was made to combine the above references because threaded surfaces allow for a full sealing of the two components and for a "quick-connect/disconnect" of the components.

5. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hooper et al. (US Patent no. 5,257,622) in view of Carson (US Patent no. 6,377,856).

Hooper et al. substantially described the invention as claimed except for the isodiametric property of the lead. Carson describes a method for implanting a medical lead in which it is taught that the lead exhibits an isodiametric shape, col 5 lines 10-11. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have a lead with out a changing in diameter since it was known in the art that the diameter of a lead is uniform.

6. Claims 7 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hooper et al. (US Patent no. 5,257,622) in view of Belden et al. (US Patent no. 6,968,235).

In regards to claims 7 and 23, Hooper et al. substantially describes the invention as claimed except for the sleeve for insertion into the header lumen. Belden et al. describes a mechanism for interconnecting electrical leads to an implantable medical device. The mechanism described by Belden et al. uses a protective sleeve 128 around

a lead 122 with a locking mechanism 164 that fits snugly into internal lock 168 of connector block 12, col 9 lines 10-15. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to encase the electrical lead in a protective sleeve for insertion into the header to provide additional sealing to prevent ingress of body fluids into the header.

7. Claims 16 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hooper et al. (US Patent no. 5,257,622) in view of Julian (US Patent no. 5,489,225).

In regards to claims 16 and 27, Hooper et al. substantially describes the device as claimed except for the use of the O-ring. Julian describes terminal for connecting an electrical lead connector pin to an implantable medical device such as a defibrillator, col 4 lines 26-28. A header 66 has a cavity for a lead connector 60 in which an O-ring seal 56 and O-ring groove 58 are utilized, col 6 lines 31-37. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use an O-ring as part of the connector in order to better prevent intrusion of body fluids into the electrical connector space.

Allowable Subject Matter

Claims 2, 3, 8, 9, 11-15, 17-20, 24, 26, and 28-31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening

claims. The structure of the limitations recited in the claims objected to above is not described nor taught, alone or in combination, in the prior art made of record.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ley et al. (US Patent no. 6,912,423) describes a connector for an electrophysiological device. Fitoussi et al (US Patent no. 6,332,633) describes a luer-type connector. Paul et al. (US Patent no. 6,112,121) describes a connector for a medical lead on an implantable medical device, which gives a positive indication of engagement. Giurtino et al. (US Patent no. 5,252,090) describes a self-locking connector between an implantable medical device and a lead. Utterberg (US Patent no. 5,047,021) describes a quick connect luer lock for a medical fitting.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272 3447. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272 6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brian T. Gedeon
Patent Examiner
Art Unit 3766



Robert E. Pezzuto
Supervisory Patent Examiner
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BTG